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Proposed Re-evaluation Decision PRVD2010-20

Copper 8-quinolinolate

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the wood preservative copper 8-quinolinolate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority the *Pest Control Products Act* and Regulations, is proposing continued registration for antimicrobial and remedial wood preservation uses of copper 8-quinolinolate in Canada.

An interim occupational risk assessment of the antisapstain uses of copper 8-quinolinolate was previously conducted by the PMRA. Results from this risk assessment were published in the Re-evaluation Decision *Re-evaluation Antisapstain Use for 2-(thiocyanomethylthio) Benzothiazole (TCMTB), Copper-8-quinolinolate, Borax and Disodium Octaborate Tetrahydrate*, RRD2004-08, and additional data were required in order to refine the assessment. The refined assessment will be conducted under a separate initiative, and will address risks to occupational handlers from the antisapstain uses. An assessment of ecological exposure and risk from antisapstain uses will also be conducted by the PMRA separately. On this basis, the current document will focus on occupational handler, postapplication (occupational and residential) and environmental exposure and risk from the antimicrobial and remedial wood preservation uses of copper 8-quinolinolate, as well as residential postapplication exposure from the antisapstain uses.

An evaluation of available scientific information found that products containing copper 8-quinolinolate registered for antimicrobial and remedial wood preservation uses do not present unacceptable risks to human health or the environment when used according to label directions. The evaluation of the available scientific information found that the end-use products containing copper 8-quinolinolate registered for antisapstain uses does not pose risks of concern to homeowners coming into contact with treated wood, when the products are used according to label directions. As a condition of the continued registration of copper 8-quinolinolate uses, new risk-reduction measures must be included on the label of products registered in Canada. Additional data are being requested as a result of this re-evaluation.

This proposal affects all end-use products containing copper 8-quinolinolate registered in Canada. Once the re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for copper 8-quinolinolate and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of copper 8-quinolinolate.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health *and* the environment. Regulatory Directive DIR2001-03, *Pest Management Regulatory Agency Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Copper 8-quinolinolate, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1 (antimicrobial and remedial wood preservation uses). This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 2007 RED, the USEPA concluded that copper 8-quinolinolate was eligible for reregistration provided risk-reduction measures were adopted. The USEPA also conducted an evaluation of registered agricultural uses of copper pesticides, including products containing copper 8-quinolinolate, in the United States, and published a RED document for coppers in 2009. This document includes updated acute toxicology profiles for all copper salts and label requirements relating to user safety recommendations. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in the 2007 RED were an adequate basis for the re-evaluation of the antimicrobial and remedial wood preservation uses of copper 8-quinolinolate in Canada. The 2007 RED was also an adequate basis for the evaluation of risks from residential exposure to copper 8-quinolinolate from the registered antisapstain uses of this chemical. As noted above, risks to occupational handlers, as well as ecological risks from the antisapstain uses of copper

8-quinolinolate are being considered under a separate initiative by the PMRA, and results from these assessments will be communicated in a separate document.

For more details on the information presented in this overview, please refer to the Science Evaluation of this consultation document.

What Is Copper 8-quinolinolate?

Copper 8-quinolinolate is a wood preservative that is used to control decay, mold and termites on finished wood products, and sapstain in freshly cut lumber and timber in transit and storage. Copper 8-quinolinolate is applied using dip, brush or spray equipment by commercial applicators.

Health Considerations

Can Approved Uses of Copper 8-quinolinolate Affect Human Health?

Copper 8-quinolinolate is unlikely to affect your health when used according to the revised label directions.

Workers can be exposed to copper 8-quinolinolate when handling the commercial class end-use product or when coming into contact with treated wood. Homeowners can be exposed to copper 8-quinolinolate when coming into contact with treated wood (for example, construction lumber), or through the consumption of food (indirect food contact via treated wooden containers used for food storage). The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that the antimicrobial and remedial wood preservation uses of copper 8-quinolinolate were unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Environmental Considerations

What Happens When Copper 8-quinolinolate Is Introduced Into the Environment?

Copper 8-quinolinolate is unlikely to affect non-target organisms when used according to the revised label directions.

Aquatic organisms could be exposed to copper 8-quinolinolate in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. In this screening level assessment, the resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some potential risks of concern.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of copper 8-quinolinolate, the PMRA is proposing further risk-reduction measures for the label product registered for antimicrobial and remedial wood preservation uses.

Human Health

- Additional protective equipment to protect handlers
- Prohibition of the use of copper 8-quinolinolate-treated wooden boxes/trays for the storage and transportation of food items
- Personal hygiene practice

Environment

- Additional advisory label statements to reduce potential surface and groundwater contamination
- Advisory statements regarding the potential toxicity to non-target organisms

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Next Steps

Before making a final re-evaluation decision on copper 8-quinolinolate, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

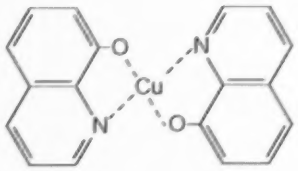
1.0 Introduction

Following the re-evaluation announcement for the wood preservative copper 8-quinolinolate, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses currently registered in Canada, with the exception of use on tomato, grape and other plant stakes.

The PMRA used recent assessments of copper 8-quinolinolate from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for copper 8-quinolinolate, dated September 2007, the RED document for coppers, dated May 2009, as well as other information on the regulatory status of copper 8-quinolinolate in the United States can be found on the USEPA Pesticide Registration Status page at www.regulations.gov (Docket ID. EPA-HQ-OPP-2007-0556 and EPA-HQ-OPP-2005-0558).

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Copper 8-quinolinolate
Function	Wood preservative fungicide
Chemical family	Quinoline
Chemical name	
1 **International Union of Pure and Applied Chemistry (IUPAC)**	Bis(quinolin-8-olato)copper (I), Cupric 8-quinolinoxide
2 **Chemical Abstracts Service (CAS)**	Bis(8-quinolinolato-N^1,O^8)copper
CAS Registry Number	10380-28-6
Molecular formula	$C_{18}H_{12}CuN_2O_2$
Structural formula	
Molecular weight	351.9 amu

Based on the manufacturing process used, contaminants of human health or environmental concern as identified in the *Canada Gazette*, Part II, Vol. 139, No. 24, SI/2005-114 (2005-11-30), including TSMP Track 1 substances, are not expected to be present in the technical product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	43.45×10^{-10} mm Hg
Henry's law constant	2.31×10^{-4} Pa·m^3·mol
UV–visible spectrum	Not expected to absorb at $\lambda > 410$ nm
Solubility in water	0.07 mg/L
***n*-Octanol–water partition coefficient**	$\log K_{ow} = 2.46$
Dissociation constant	$pK_1 = 12.2$ $pK_2 = 11.2$

2.3 Comparison of Use Patterns in Canada and the United States

Copper 8-quinolinolate is a wood preservative registered in Canada to control decay, mold and termites on finished wood products (for example, fruit and vegetable boxes, mushroom trays, construction lumber, millwork, fence posts, etc.). These uses are referred to as antimicrobial and remedial wood preservation uses in the document. Copper 8-quinolinolate is also registered for the control of sapstain in freshly cut lumber and timber in transit and storage (antisapstain uses). End-use products registered in Canada are formulated as solutions. Copper 8-quinolinolate is applied at a concentration of up to 1.0% (v/v) on finished wood products using dip, brush or spray equipment. It is also applied at a concentration of up to 0.0675% (v/v) on freshly cut lumber and timber in transit or storage using dip tank application technology. As these are commercial class products, application occurs in commercial treatment facilities. While there are no domestic class products registered for use in Canada, residential exposure can occur through contact with the treated wood or finished wood products (for example, construction lumber, decks and playsets). In both the United States and Canada, treated wood may have ground contact or come into contact with water or food.

The American and Canadian use patterns were compared. The Canadian formulation type, use sites, guarantees, application methods and application rates for copper 8-quinolinolate are encompassed by the American use pattern, with the exception of the Canadian use of copper 8-quinolinolate to treat wooden containers used for storage and transport of food items (mushrooms, fruits and vegetables). This use is being cancelled by registrants in the United States. The American use pattern is more extensive than the Canadian use pattern, and includes use on industrial textiles, in-can paint preservation, pulp and paper, kraft paper, and adhesives

and glue. Based on this comparison of use patterns, it was concluded that the USEPA RED for copper 8-quinolinolate is an adequate basis for the re-evaluation of uses of copper 8-quinolinolate in Canada.

All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of copper 8-quinolinolate, with the exception of the use of copper 8-quinolinolate on tomato, grape and other plant stakes. Appendix II lists all copper 8-quinolinolate products that are registered as of 19 May 2010, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2007 RED, the USEPA concluded that the end-use products formulated with copper 8-quinolinolate met the safety standard under the *American Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the revised product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to copper 8-quinolinolate may occur through consumption of food (from the contact of food items with wooden containers used for transport or storage), while handling or applying the product or by contact with treated wood. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

The USEPA's toxicological endpoints for assessing risk to human health are summarized in Appendix III.

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure. This is compared to a target margin of exposure incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated margin of exposure is less than the target margin of exposure, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Workers can be exposed to copper 8-quinolinolate when handling or applying the pesticide and when handling treated wood.

3.1.1.1 Handler Exposure and Risk

Long-term exposure to copper 8-quinolinolate from the wood preservative uses was not expected; therefore, the USEPA did not assess the occupational risk from long-term exposure to this chemical.

Among the scenarios assessed in the RED, the following were considered relevant to the Canadian situation:

- Diptank operator
- General wood preservation by brush (this scenario was considered conservative to application using spray equipment)
- Application of wood coatings by professionals by brush/roller or low pressure sprayer

Handler exposure analyses were performed assuming baseline personal protective equipment (long-sleeved shirt and long pants), with or without chemical-resistant gloves. Short-/intermediate-term dermal and short-/intermediate-/long-term inhalation exposures and risks were based on maximum copper 8-quinolinolate application concentrations ranging from 0.8 % to 3.3% in solution.

Results indicated that occupational dermal exposures and risks are not of concern for workers wearing baseline protective equipment and chemical-resistant gloves. Based on this, the USEPA required workers to wear chemical-resistant gloves when handling copper 8-quinolinolate products. Results indicated that occupational inhalation exposures and risks are not of concern.

Although the Canadian maximum application concentration is 1.25 times higher than the rate assessed by the USEPA for the application of wood coatings, the estimated margins of exposure are large enough to provide sufficient protection to account for the difference between the Canadian and the American rates. Based on the above, the RED adequately addressed exposure scenarios associated with the antimicrobial and remedial wood preservation uses of products containing copper 8-quinolinolate in Canada, and conclusions derived from the RED apply to the Canadian situation.

Copper 8-quinolinolate was found to be an eye irritant and acutely toxic via the inhalation route. Incident reports listed in the RED reported dermal, eye and respiratory track irritation. Based on the above, the PMRA is proposing the requirement of coveralls over a long-sleeved shirt and long pants, chemical-resistant footwear, chemical-resistant gloves, goggles and a respirator for workers handling the product, and during clean-up, maintenance and repair activities. Based on precautionary statements required by the USEPA for all products containing copper salts in their 2009 RED, the PMRA is also proposing the requirement of precautionary statements related to good hygiene practices on the label of products containing copper 8-quinolinolate. The proposed label amendments are listed in Appendix IV.

3.1.1.2 Postapplication Exposure and Risk

In Canada, postapplication exposure may occur from workers coming into contact with copper 8-quinolinolate-treated wood.

Among the scenarios assessed in the RED, the following were considered relevant to the Canadian situation:

- Trim saw operator
- Clean-up crew

Exposure analyses were performed using surrogate unit exposure data and assuming baseline personal protective equipment (long-sleeved shirt and long pants), with chemical-resistant gloves. Short-/intermediate-term dermal and short-/intermediate-/long-term inhalation exposures and risks were based on a maximum copper 8-quinolinolate application concentration of 34.18% in solution.

Results indicated that postapplication dermal and inhalation exposures and risks are not of concern.

The USEPA also identified exposure of construction workers installing preserved wood as another postapplication exposure scenario. However, available data was not sufficient to quantitatively assess exposure and risk associated with this function. Trim saw operators were expected to have larger dermal and inhalation exposures than the construction worker. Because acceptable margins of exposure were estimated for trim saw operators, risks of concern are not anticipated for construction workers installing treated wood. Based on above, the USEPA concluded that there were no occupational postapplication risks of concern, and no mitigation measures were required.

The 2007 RED adequately addressed potential postapplication exposure scenarios associated with the Canadian antimicrobial and remedial wood preservation uses of copper 8-quinolinolate. No additional mitigation measures are proposed by the PMRA with respect to postapplication exposure of workers.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Residential exposure is estimated using the margin of exposure approach described in Section 3.1.1.

There are no domestic class products containing copper 8-quinolinolate registered in Canada. Based on this, adults and children can be exposed to copper 8-quinolinolate when coming into contact with treated wood, or through inhalation or incidental ingestion of wood dust. Toddlers can also be exposed via "hand-to-mouth" and "object-to-mouth" activities, inhalation of soil dust, dermal contact with soil, or through incidental soil ingestion.

Residential postapplication exposure is expected to occur over a short-term duration, as episodic events; thus, intermediate-term residential postapplication exposure was not assessed. At the time of the 2007 RED, there were no data available to estimate exposure to adults and children from wood dust or soil contaminated with copper 8-quinolinolate.

Short-term dermal and incidental oral exposures and risks for toddlers coming into contact with treated wood were assessed. Children were chosen to represent the maximum exposed individuals in the USEPA's assessment. Exposure and risk assessments were based on maximum copper 8-quinolinolate application concentrations of 2.3% in solution. Results indicated that residential postapplication exposures and risks are not of concern.

The 2007 RED adequately addressed potential residential exposure associated with the Canadian antimicrobial, remedial wood preservation and antisapstain uses of copper 8-quinolinolate. The exposure of toddlers through dermal and incidental oral (hand-to-mouth) contact with treated wood is expected to be the worst-case exposure scenario for residential exposure, and risks estimates were above the target MOE. On this basis, residential exposure to copper 8-quinolinolate from treated wood, wood dust or contaminated soil is not expected to be of concern. The PMRA requires no further mitigation measures with respect to residential exposure.

3.1.2.2 Exposure From Food and Drinking Water

Copper 8-quinolinolate is not registered for food use in Canada. However, the application of copper 8-quinolinolate on wooden containers used for the transport or storage of mushrooms, fruits and vegetables, or on trays used to grow mushrooms may result in indirect food contact. Copper 8-quinolinolate is also currently registered for use on tomato, grape and other plant stakes; however, this use is being voluntarily discontinued by the registrant.

Copper 8-quinolinolate is not registered for potable water treatment uses and effluents containing this chemical are not anticipated to have an impact on freshwater environments when used according to label directions. Therefore, a drinking water exposure and risk assessment was not conducted by the USEPA. The PMRA searched the available Canadian water monitoring data, however, no data are available for copper 8-quinolinolate.

The USEPA did not quantitatively assess risks from dietary exposure to copper 8-quinolinolate from food items (for example, mushrooms) coming into contact with treated wooden trays. Based on available data and on the fact that mushrooms are typically grown on compost (which is typically not reused), it was determined unlikely that the use of copper 8-quinolinolate to treat wooden mushroom trays would result in residues in mushrooms. The USEPA concluded that there were no dietary risks of concern for this scenario. The USEPA dietary risk assessment and conclusions are considered to be relevant to the use of copper 8-quinolinolate on wooden trays used to grow mushrooms in Canada, and risks from this use are not expected to be of concern.

The use of copper 8-quinolinolate on wooden containers used for the storage and transport of mushrooms, fruits and vegetables is not covered by the USEPA's assessment. Because fruits and vegetables may remain in wooden containers for more than 24 hours, the information currently available is insufficient to support the use of copper 8-quinolinolate-treated containers for the transport or storage of food items. Based on this, the PMRA is proposing that product labels be amended to remove this use. The proposed label amendments are listed in Appendix IV.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to copper 8-quinolinolate. Short- and intermediate-tem aggregate risk assessments are comprised of contributions from food, drinking water and non-occupational exposure (dermal, inhalation).

As noted in Section 3.1.2.2, exposure to copper 8-quinolinolate from food and drinking water is expected to be negligible based on the revised Canadian use pattern (treated mushroom trays as the only food-contact use); thus, dietary exposure is not expected to contribute to aggregate exposure for this chemical. In Canada, toddlers may be exposed to copper 8-quinolinolate via the dermal and incidental oral (hand-to-mouth) routes from contact with treated wood. This exposure scenario was considered to be the worst-case scenario for aggregate exposure, and was assessed by the PMRA using the margins of exposure calculated in the 2007 RED for short-term dermal and incidental oral exposure for toddlers.

Results indicated that aggregate exposure to copper 8-quinolinolate from contact with treated wood is not of concern in Canada. The PMRA requires no further mitigation measures with respect to aggregate exposure.

3.1.3 Cumulative Effects

The USEPA has not determined whether copper 8-quinolinolate has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that copper 8-quinolinolate does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Fate Characteristics

Copper 8-quinolinolate was found to be persistent in soil, but did not show any tendency to migrate from top soils. On this basis, this chemical has the potential to reach the aquatic environment by runoff. Leaching into groundwater is, however, not expected. Copper 8-quinolinolate was found to photodegrade in water in 60 to 96 hours in a laboratory study. Based on available data, copper 8-quinolinolate is unlikely to bioaccumulate. There was a lack of robust leaching data for copper 8-quinolinolate-treated wood at the time of the RED, and a confirmatory wood leaching study was required by the USEPA.

It is proposed that similar wood leaching data be required by the PMRA (see Appendix I).

3.2.2 Environmental Risk Assessment

In Canada, copper 8-quinolinolate-treated wood may come in contact with the ground (for example, stakes and fence posts); therefore, non-target organisms may be exposed to this chemical due to potential leaching from treated wood to soils and potential runoff to surface waters. Leaching from the treated wood into the aquatic environment (for example, docks) may also result from the use of copper 8-quinolinolate as a wood preservative.

Risk assessments for birds and mammals were not performed because, based on available data, copper 8-quinolinolate was not expected to be acutely toxic to these organisms. As a result, the potential for copper 8-quinolinolate to have adverse effects on birds and mammals was expected to be low. Exposure to terrestrial plants is also not expected based on the use pattern.

To assess the ecological risk of copper 8-quinolinolate to aquatic non-target plants and animals, the USEPA calculated risk quotients (RQs) based on appropriate toxicity endpoints and expected environmental concentrations (EECs) and compared the resulting RQs to corresponding levels of concern (LOCs). In the USEPA assessment, expected environmental concentrations for aquatic organisms were generated by modelling the release of copper 8-quinolinolate from a wooden dock into water. The USEPA determined the following:

- Acute RQs exceeded the LOC for aquatic plants; however, the USEPA considered that aquatic EECs were conservative, and that risks to plants were not of concern.

A risk assessment for insects was not performed in the 2007 RED due to a lack of data; however, based on data available in the PMRA database, copper 8-quinolinolate was found to be only slightly toxic to bees. Chronic risk assessments were not conducted for freshwater fish, as well as freshwater and estuarine/marine invertebrates, and acute and chronic risk assessments were not conducted for estuarine/marine fish, due to lack of data. Based on the copper 8-quinolinolate use pattern and the chemical's relatively short aqueous photolysis half-life, chronic exposure is not expected.

The American use pattern for copper 8-quinolinolate encompasses the Canadian use pattern, and the conclusions derived from the RED are considered relevant to Canada. Based on the USEPA's assessment and the PMRA's general practices, additional advisory label statements are proposed. Proposed label amendments are listed in Appendix IV.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, namely, CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative).

During the re-evaluation process, copper 8-quinolinolate was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, and evaluated against the Track 1 criteria for persistence and bioaccumulation. In order for copper 8-quinolinolate or its transformation products to meet Track 1 criteria, all four criteria must be met.

Copper 8-quinolinolate meets the Track 1 criterion for persistence, as its half-life value for soil (> 365 days) is above the cut-off value of 182 days. Copper 8-quinolinolate does not, however, meet the Track 1 criterion for bioaccumulation, as its octanol-water partition coefficient (log K_{ow} = 2.46) is below the Track 1 criterion of 5. Given that copper 8-quinolinolate does not meet all Track 1 criteria, it is not considered a Track 1 substance.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of copper 8-quinolinolate, contaminants in the technical are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has concluded that the technical grade copper 8-quinolinolate does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

4.0 Incident reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

There were no incident reports submitted for copper 8-quinolinolate as of 19 May 2010.

5.0 International Status of Copper 8-quinolinlate

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 33 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Based on the available information on the status of copper 8-quinolinolate in other countries, this chemical (as "oxine copper") is registered for the control of sapstain in wood in Australia.

Copper 8-quinolinolate (as "oxine copper") was not supported by its sponsor when reviewed as part of the European Commission Programme and, as a result, products containing this chemical were to be withdrawn from the market.

In 2007, the United States assessed the registration of all uses of copper 8-quinolinolate and concluded that using this chemical as a pesticide does not result in unreasonable adverse effects to human health or the environment, provided the risk-reduction measures recommended in the 2007 RED document were implemented.

6.0 Proposed Re-evaluation Decision

The PMRA has determined that the antimicrobial and remedial wood preservation uses of copper 8-quinolinolate are acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The label of Canadian end-use products must be revised to include the label statements listed in Appendix IV. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. The registrant of the technical grade active ingredient is required to submit data as a condition of continued registration under Section 12 of the *Pest Control Products Act*. Appendix I lists data requirements.

Based on the assessment of residential exposure and risk from the antisapstain uses of copper 8-quinolinolate, residential exposure to this chemical is not of concern. The acceptability for continued registration of products containing copper 8-quinolinolate registered for antisapstain uses in Canada will be communicated in separate documents after the completion of the occupational and environmental risk assessments for those uses.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, *Pest Management Regulatory Agency Re-evaluation Program*, and DACO tables can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxiques-toxics/.

The USEPA RED documents for copper 8-quinolinolate and coppers (Docket folder EPA-HQ-OPP-2007-0556 and EPA-HQ-OPP-2005-0558) are available on the USEPA Pesticide Registration Status page at www.regulations.gov.

List of Abbreviations

λ	wavelength(s)
amu	atomic mass units
bw	body weight
CAS	Chemical Abstracts Service
cPAD	chronic population adjusted dose
DACO	data code
EEC	expected environmental concentration [also estimated environmental concentration]
FQPA	*Food Quality Protection Act*
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LOAEL	lowest observed adverse effect level
LOC	level of concern
m^3	metre(s) cubed
mg	milligram(s)
mm Hg	millimetre mercury
MOE	margin of exposure
mol	mole
nm	nanometre
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
Pa	Pascal
pK_a	dissociation constant
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
RfD	reference dose
RQ	risk quotient
SF	safety factor
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v	volume

Appendix I Additional Data Requirements

The following data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrant of copper 8-quinolinolate is required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter the PMRA will send.

- DACO 8.6 – Other studies/data/reports (wood leaching study) (Guideline: American Wood Protection Association (AWPA) Method E11-06, Standard Method of Determining the Leachability of Wood Preservatives Immersed in Water, 2006)

Appendix II Registered Products Containing Copper 8-quinolinolate as of 19 May 2010

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
25882	Technical	Tanabe USA Inc.	Copper-8-quinolinolate	Dust	96
12143	Commercial	IBC Manufacturing Company	PQ-8 Liquid Fungicide Concentrate	Solution	5.4
15314	Commercial	IBC Manufacturing Company	PQ-57 Wood Preservative	Solution	5.0

Appendix III USEPA Toxicological Endpoints for Copper 8-quinolinolate Health Risk Assessments

Exposure Scenario (route and period of exposure)	Dose (mg/kg bw/day)	Study	UF/SF or Target MOE [a]
Acute Dietary (females 13-49)	No appropriate endpoints were identified that represented a single dose effect. Therefore, this risk assessment was not conducted.		
Chronic Dietary (all populations)	NOAEL = 5 Chronic RfD (cPAD) = 0.05	Subchronic oral toxicity in dog LOAEL = 50 mg/kg bw/day, based on vomiting, decreased total plasma protein and albumin, and reddened mucosa and hyperemia in the stomach and small intestine	FQPA SF = 1[b] UF = 100[c]
Incidental Oral Short- (1-30 days) / Intermediate-term (1-6 months)	Maternal NOAEL = 200	Prenatal developmental toxicity in rat Maternal LOAEL = 800 mg/kg/day, based on clinical signs of toxicity and decreased body weight gain in maternal rats	FQPA SF = 1[b] MOE = 100[c]
Dermal Short- (1-30 days) / Intermediate-term (1-6 months)	Systemic NOAEL = 200	28-day dermal toxicity in rat Systemic LOAEL = 1000 mg/kg/day, based on necrosis of thymic lymphocytes. No evidence of dermal irritation from either this or the acute dermal study	MOE = 100[c]
Inhalation (all durations)	NOAEL = 5 (inhalation absorption factor = 100%)	Subchronic oral toxicity in dog LOAEL = 50 mg/kg bw/day, based on vomiting, decreased total plasma protein and albumin, and reddened mucosa and hyperemia in the stomach and small intestine	MOE = 1 000[d]
Carcinogenicity	Copper 8-quinolinolate had not been formally classified for carcinogenicity		

[a] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments, MOE refers to desired margin of exposure for occupational or residential assessments.

[b] FQPA SF set to 1× based on no evidence of primary developmental effect, primary reproductive effect, teratogenicity, reproductive toxicity, increased susceptibility of offspring or neurotoxicity

[c] 10 fold interspecies extrapolation; 10 fold intraspecies variation

[d] 10 fold interspecies extrapolation; 10 fold intraspecies variation; 10 fold route-to-route extrapolation

NOAEL = no observed adverse effects level; LOAEL = lowest observed adverse effects level; FQPA SF = Food Quality Protection Act Safety Factor; MOE = margin of exposure; RfD = reference dose; PAD = population-adjusted dose.

Appendix IV Proposed Label Amendments for Products Containing Copper 8-quinolinolate

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

I) The label of the PQ-57 Wood preservative product (Registration Number 15314) must to be amended to remove all references to use on tomato, grape or other plant stakes, and on fruit and vegetable boxes, baskets and bins.

II) The label of the PQ-8 Liquid Fungicide Concentrate (Registration Number 12143) and the PQ-57 Wood Preservative product (Registration Number 15314) must be amended to include the following statements to further protect workers.

The following statement is to be included in a section entitled **PRECAUTIONS**.

> Remove personal protective equipment immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.
>
> If gloves are required on the label, wash the outside of gloves before removing.
>
> Remove clothing/personal protective equipment immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
>
> For cleaning/maintaining personal protective equipment, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.
>
> Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them.
>
> Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

III) The label of the PQ-57 Wood Preservative product (Registration Number 15314) must to be amended to include the following statements to further protect workers and the environment.

A) The following statement must be included in a section entitled **PRECAUTIONS**.

Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant footwear, chemical-resistant gloves, goggles, and a NIOSH-approved respirator with a dust/mist filter when handling or applying the product, and during clean-up, maintenance and repair activities.

B) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

Treated wooden trays are only to be used to grow mushrooms. The trays are not to be used to store or transport mushrooms, fruits or vegetables.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

Dip tanks and drip aprons must be roofed, paved and drained to prevent dilution and loss of treatment solution.

Store treated lumber on a roofed drip pad until dripping has ceased. Slope lumber on the drip pad to expedite drainage and to ensure that no puddles remain on the surface of the wood. Manage drippage and other related wastes to prevent release in the environment.

DO NOT expose treated lumber to rains immediately after treatment. **DO NOT** float treated lumber in lakes, rivers, streams or oceans.

For further information on storage, handling and disposal of treated wood, contact the manufacturer of this product or the provincial regulatory agency.

C) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**.

Toxic to aquatic organisms.

References

A. Information Considered in the Chemistry Assessment

Studies/Information Submitted By Applicant/Registrant (Unpublished)

PMRA Document Number: 1723180
Reference: 1994, CUQ-TMA-1 Product Chemistry of Copper 8-Qunolinolate – Physical and Chemical Properties, DACO: 2.14

PMRA Document Number: 1722950
Reference: 1994, CUQ-TMA-1 Product Chemistry of Copper 8-Quinolinolate – Manufacturing Process and Discussion of Impurities, DACO: 2.11

PMRA Document Number: 1722952
Reference: 1994, CUQ-TMA-1 Product Chemistry of Copper 8-Quinolinolate – Composition of Five Batches of Technical Material, DACO: 2.13

B. Information Considered in the Environmental Risk Assessment

Additional Information Considered

Published Information

PMRA Document Number: 1936602
Reference: Department for Environment, Food and Rural Affairs, Pesticide Safety Directorate, York, UK. 1989. Evaluation Document on Oxine Copper.